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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Rodrigo Franco

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EXAMINER

DANG, IAN D

ART UNIT

PAPER NUMBER

1647

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,531	<b>Applicant(s)</b> FRANCO ET AL.	
	<b>Examiner</b> IAN DANG	<b>Art Unit</b> 1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-13,17,18,20,40,41,43,46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-6,8-13,17,18,20,40,41,43,46 and 47 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Status of Application, Amendments and/or Claims***

The amendment of 06 September 2006 has been entered in full. Claims 7, 14-16, 19, 21-39, 42, 44, and 45 have been cancelled and claims 4, 18, 20, and 41 have been amended.

Claims 1-6, 8-13, 17, 18, 20, 40, 41, 43, 46, and 47 are pending.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3, 4-6, 8-10, and 18 drawn to an isolated sodium channel type III  $\alpha$  subunit (mNa<sub>v</sub>1.3  $\alpha$  subunit) polypeptide, an isolated mNa<sub>v</sub>1.3  $\alpha$  subunit nucleic acid molecule that encodes a sodium channel type III  $\alpha$  subunit, an expression vector, and a host cell, and a method of modulating a mNa<sub>v</sub>1.3  $\alpha$  subunit polypeptide activity in a cell.

Group II, claim(s) 11-13 and 17, drawn to an agent which preferentially binds to the mNa<sub>v</sub>1.3  $\alpha$  subunit polypeptide and a pharmaceutical composition comprising the agent.

Group III, claim(s) 20 and 40, drawn to a method for identifying an agent that modulates the activity of a mNa<sub>v</sub>1.3  $\alpha$  subunit polypeptide.

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Group IV, claim(s) 41 and 43, drawn to a method for identifying an agent useful in the treatment of a disorder related to sodium current modulation comprising providing a sodium channel comprising a  $mNa_v1.3 \alpha$  subunit polypeptide.

Group V, claim(s) 46 and 47, drawn to a method for treating a subject having a disorder related to sodium channel current comprising identifying an agent that selectively binds a  $mNa_v1.3 \alpha$  subunit polypeptide and administering to a subject in need of such treatment a pharmacological agent.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the methods of Groups I-V do not share the same or corresponding special technical feature because methods do not share a specific technical feature because each of the methods has different starting materials, methods steps, and/or goals, and the agent and the isolated sodium channel do not share a special technical feature because they are products with different structures and functions. For instance, the invention of Group I is drawn to a method for identifying an agent that modulates the activity of a  $mNa_v1.3 \alpha$  subunit polypeptide, the invention of Group III is drawn to method for identifying an agent that modulates the activity of a  $mNa_v1.3 \alpha$  subunit polypeptide, the invention of Group IV is drawn to a method for identifying an agent useful in the treatment of a disorder related to sodium current modulation comprising providing a sodium channel comprising a  $mNa_v1.3 \alpha$  subunit polypeptide, the invention of Group V is drawn to a method for treating a subject having a disorder related to sodium channel current comprising identifying an agent that selectively binds a  $mNa_v1.3 \alpha$  subunit polypeptide and administering to a subject in need of such treatment a pharmacological agent. Therefore, each method represents an independent inventive concept.

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

### Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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If Applicants elect Group II, they must further elect one of the following species for an agent which preferentially binds to the  $mNa_v1.3$   $\alpha$  subunit polypeptide:

- a) Small molecule
- b) A Nucleic acid
- c) A protein

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: 13.

The following claim(s) are generic: claim 12.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the agents listed in claim 12 do not share a common structural feature.

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### **Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
August 11, 2008

/Robert Landsman/  
Primary Examiner, Art Unit 1647